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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
COPPINS, JANET L	

ART UNIT	PAPER NUMBER
1625	10

DATE MAILED: 10/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,869	SHAYMAN, JAMES A.	
	Examiner	Art Unit	
	Janet Coppins	1625	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-31 pending in the instant application.

Response to Amendment

1. Receipt is acknowledged of Applicant's Amendment A, submitted 7/14/03, which has been reviewed by the Examiner and entered of record in the file as Paper No. 9.

Accordingly, claims 11, 23, and 31 have been amended.

Response to Arguments

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 6, 8, 9, 11, 18, 20-23, 26, and 28-31 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

4. Firstly, the Examiner would like to address the inadvertent inclusion of the language "diabetic complicating diseases" in the second paragraph of the enablement rejections. The Examiner had intended to delete the sentence containing said language, and apologizes for any inconvenience.

(a) The Examiner maintains the rejections of claims 8, 20, and 28, directed to a method of treating microbial or viral infections. The specification is not enabled for all

microbial or viral infections, yet the claim reads that any and all microbial and/or viral infections could be treated using the instant claimed process. In order to practice the claimed invention, one skilled in the art would have to speculate which microbial or viral infection could be treated or prevented using the amino ceramide-like compounds found in the instant claims. Further, the phrase "microbial" encompasses infections caused by not only bacteria, but fungi and yeast, none of which has been specified. Applicants have traversed the rejection, arguing that an application need not teach, and preferably omits, what is well known to those of skill in the art, however neither the present specification nor the art teach the use of an amino ceramide-like compound of claim 1 for the treatment of all microbial or viral infections diseases, such as bacteria, viruses, parasitic organisms, etc. Thus, without working examples or proper guidance as how to use the compound for the treatment of such microbial or infectious diseases as not disclosed in the specification, it would require undue experimentation by one skilled in the art to use a product as disclosed for treatment of all of the possible diseases. The Examiner suggests narrowing the scope of the aforementioned claims to include diseases that are enabled by the disclosure, for example, those specific diseases discussed in the first paragraph on page 10 of the "Response."

(b) Likewise, the Examiner maintains the enablement rejections of claims 6, 9-11, 18, 21-23, 26, and 29-31 for the specification not being enabled for treating all tumors or cancers. Presently over 3000 different types of specific cancers exist. The various types of cancers have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. For example, claim 6 recites "a method of inhibiting the growth of cancer cells," implying all cancers, but it not enabled for such. In order to provide proof of utility with

regard to drugs and their uses, either clinical *in vivo* or *in vitro* data correlative to *in vivo* applicability or a combination of these can be used. However, the data must be such as to convince one of ordinary skill in the art that the proposed utility is sufficiently established as set forth in full, clear and exact terms in the disclosure. Even if the application need not teach, and preferably omits, what is well known to those of skill in the art, the claims must give some indication as to the cancers that the Applicants are intending to treat utilizing the instant invention, i.e. Applicants must set definite boundaries on protection sought (In re Wakefield, 164 USPQ 636). In order to obviate the enablement rejection, the Examiner suggests narrowing the scope of the claims by incorporating some cancers that the disclosure is enabled for.

(c) Claims 9, 21, and 29 stand rejected for reciting the phrase, "A method for treating a patient having a drug resistant tumor..." however this is based on a disclosure which is not enabling (see In re Wands, 8 USPQ2d 1400, 1988), because the Applicants do not indicate in the disclosure that the instant claimed compounds are superior to all other anti-cancer prodrugs. Sufficient evidence is lacking which would show a quantitative advantage over all other compounds that are known to have therapeutic uses for treating malignant tumors. The lack of evidentiary data prevents one of ordinary skill in the art from accepting any therapeutic regimen on its face, especially above other known prodrugs. As the Applicants have not provided any data as to the efficacy or quantitative advantage of the instant claimed compound over all other anti-cancer drugs, the Examiner maintains the rejections.

(d) Claims 11, 23, and 31 stand rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure that is not enabling. The recited "vaccination method," critical or essential to the practice of the invention, but not included in the claims, is still not enabled by the

disclosure. Applicants argue that page 10 of the specification teaches a vaccination method, however the specification reads that, "...cancer cells are removed from the patient" yet gives no indication as to whether the cells are removed by surgery, what type of cells are being removed, etc. As stated before, the attenuating toxin has not been identified for vaccination, and more than routine experimentation is required to arrive at the invention (vaccination method) as intended by the Applicants. The data must be such as to convince one of ordinary skill in the art that the proposed utility is sufficiently established as set forth in full, clear and exact terms in the disclosure. The Examiner maintains the 112, first paragraph rejections of said claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7-17, 19, 20-24, and 27-31 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) In view of the Applicants' persuasive arguments, the Examiner withdraws the 112, second paragraph rejections of Claims 1, 12, and 24, *only* with respect to the definition of the tertiary amine group for R_3.

(b) Claims 1 and 12 recite the phrase "...R_4 is a group that is selectively hydrolyzed in a target cell," however it is unclear what moiety is being hydrolyzed, and the functional language fails to indicate what target cell is doing the hydrolyzation. The Examiner reminds the Applicants that "Claims must stand alone to define the invention and incorporation into claims by express reference to the specification is not permitted"

(Ex parte Fressola, 27 USPQ 2d 1608). The Examiner suggests including the hydrolysable groups discussed on pages 5-6 of the specification, and including possible examples of target cells.

(c) Claims 3, 14, and 15 all recite the phrase "...wherein n is **at least** 1..." yet fail to set an upper limit for the value of n. Applicants argue that there is no ambiguity or indefiniteness in defining a chemical structure using an open-ended range, however the functional language "at least" has been found unacceptable in numerous cases, including Petrolite Corp. v. Watson. Comr. Pats., 113 USPQ 248.

(d) Claim 24 fails to define the invention properly, because the value of the variable n has not been described. While the specification may define the variable, the claim remains indefinite since it has not particularly pointed out or distinctly claimed the upper or lower limits (definition) of n. The Examiner refers once again to Ex parte Fressola.

(e) Claims 8, 20, and 28 still recite the phrase "A method for treating a patient having a microbial or viral infection..." however this functional language is vague because microbial infections consist of bacterial, fungal, or yeast-causing infections, and it is unclear what kind of infection the Applicants are intending to treat. Claims 9, 21, and 29 all still recite "A method for treating a patient having a drug resistant tumor..." yet it is unclear what type of tumor or cancer is being treated. Claims 10, 22, and 30 all still recite "A method for reducing tumor angiogenesis..." in line 1 yet fails to specify the type of tumor. The Examiner maintains the rejections because while this information may be known in the art, the claims are still unclear since they have failed to specify which infections, tumors, etc the Applicants are intending to treat.

(h) Claims 11, 23, and 31 recite in step a) the phrase, "removing cancer cells..." which is vague and indefinite because a) it is unclear how the Applicants are intending to remove the cells (i.e. *in vivo* or via surgery) and b) from what location (i.e. organ, marrow, blood, etc) and c) whether the cancer has metastasized. While the Applicants have directed the Examiner's attention to page 10 of the specification, there is still no indication as to the indefiniteness of the above a), b), and c) questions.

6. Claims 2, 4, 5, 7, 13, 16, 17, 19, and 27 rejected under 35 U.S.C. 112, second paragraph, as being dependent on base claims that stand rejected under 35 U.S.C. 112, second paragraph.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 12, 13, 24, 25 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, and 4 of U.S. Patent No. 6,030,995. However the Examiner will address this issue further when the claims are in condition for allowance.

Conclusion

9. Claims 1-31 remain rejected in the instant application.

10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Coppins whose telephone number is 703.308.4422. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703.308.4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703.746.9037 for regular communications and 703.872.9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.1235.

Janet L. Coppins
October 4, 2003

CEILA CHANG
PRIMARY EXAMINER
GROUP ~~1200~~ 1625

For Al Rotman SPE